

### **III. Remarks**

#### **A. Response to Rejection of Claims 46, 57-58, 61, 63, 64 and 66-70 Under 35 U.S.C. § 103**

Claims 46, 57-58, 61, 63, 64 and 66-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of United States Patent No. 5,750,563 to Honda, in view of United States Patent No. 5,322,689 to Hughes et al.

##### **1. Subject matter of Applicant's claimed invention**

Applicant's independent claims 46, 64 and 67 are directed to an antimicrobial composition consisting essentially of and in the form of a mixture of 0.1 to 90% by weight of a polyphenol selected from the group consisting of tannins and tannic acid and 0.1 to 30% by weight of lactic acid, the mixture containing no other generally recognized as safe flavored alcohols and is free of benzyl alcohol.

##### **2. Examiner's Response to Applicant's Previous Response**

The Examiner's response to Applicant's arguments regarding the patentability of the claims over the same rejection is as follows:

Applicant's arguments filed 4/23/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. The combination of the Honda and Hughes references cannot obviate the claimed invention since the Honda reference requires benzyl alcohol and it is expressly restricted from the claimed invention.

Regarding this argument, it remains the position of the Examiner that the combination of the Honda and Hughes patents obviates the claims. Regarding the disclosure of benzyl alcohol by Honda, the Examiner disagrees with Applicant on the importance of benzyl alcohol. The reference does not exemplify the use of the compound. Further the compound is listed with more than a dozen other compounds of equal functional equivalents. Benzyl alcohol is not a required feature of the '689 patent. In the 3 examples of the patent camphor is applied as the anesthetic compound in a concentration of 5.25 w/w %, well within the limits of the instant claims. The prior art discloses an antimicrobial composition comprising flavonoids, and carriers identical to those of the instant claims. The '563 patent discloses an [*sic*] antimicrobial agents and carriers such as

gossypetin and camphor, all within the range of concentrations from 0.1–20 w/w %. The reference is silent to the inclusion of lactic acid. The '689 patent discloses antimicrobial formulation comprising camphor, and lactic acid in a concentration from 1–8% (col. 7, lin. 40–50). This combination meets the limitations of the instant claims. For these reasons the claims remain obviated by the combination of the '563 and '689 patents.

(Action at page 5, line 7 to page 6, line 4).

**3. Comparison between the subject matter of Applicant's claimed invention and the disclosures of Honda and Hughes et al.**

As noted above, Applicant's claimed invention is directed to an antimicrobial composition consisting essentially of a mixture containing defined weight percents of a polyphenol selected from the group of tannins and tannic acid and of lactic acid. The mixture contains no other generally recognized as safe flavored alcohols and is free of benzyl alcohol. The other pending claims 57–58, 61 and 63–70 also include the limitation now set forth in claim 46.

According to Section 2111.03 of the *Manual of Patent Examining Procedure*:

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not **materially** affect the **basic** and **novel** characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551–52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1984). *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988).

(M.P.E.P. 2111.03).

The Honda patent is directed to a preparation for epidermis containing kojic acid and/or its derivative and at least one member selected from the group consisting of alcohols and polyphenols (See '563 patent, Abstract and Summary of the Invention at Column 2, lines 15–24). Kojic acid is defined as 5-hydroxy-2-hydroxymethyl-y-pyrone (Column 2, lines 32–33). It is not a tannin or tannic acid. Nor is kojic acid equivalent to lactic acid. Applicant's specification clearly discloses that Applicant's inventive antimicrobial compositions are based on GRAS (generally recognized as safe) flavoring agents. 21 C.F.R. Sections 170.3 and 182.3041 identifies GRAS ingredients approved by the FDA. Kojic acid is not GRAS approved. See *a/so* United States Patent No. 7,258,882 at column 1, lines 64–67 and column 2, line 64 to column 3, line 3). Accordingly, Applicant's composition, as claimed, cannot include kojic acid as kojic acid would materially affect the basic and novel characteristics of Applicant's claimed composition.

Honda requires the presence of kojic acid. In fact, kojic acid and/or its derivatives is the essential ingredient of the preparation disclosed by Honda.

Hughes et al. is directed to a topical oil and water emulsion composition useful for releasing an aromatic decongestant composition comprising a carboxylic copolymer and volatile aromatic compounds (Column 2, lines 26–54). Hughes et al. describes as optional components pharmaceutical actives such as benzyl alcohol (which is excluded from Applicant's claimed antimicrobial composition), as well as humectants/moisturizers. (See column 6, line 12 to column 9, line 61 and column 9, lines 41–47). In Hughes et al., lactic acid is identified as one of a number of humectants and moisturizers and is not disclosed as a preferred humectant/moisturizer for use in the compositions of the Hughes et al. invention. (See column 7, lines 39–59). Hughes et al. does not exemplify, disclose or even suggest to one of ordinary skill in the art the exclusion from the Hughes et al. composition of benzyl alcohol and other generally recognized as safe flavored alcohols, other than polyphenol.

The combination of Honda and Hughes et al. does not teach or suggest all the claim limitations. For example, Honda and Hughes et al. do not teach or suggest to one of ordinary skill in the art, Applicant's claimed composition consisting essentially of a mixture containing no other generally recognized as safe flavored alcohols other than polyphenol. Indeed, the Honda composition comprises alcohols that are identified as generally recognized as safe flavored

alcohols in Applicant's specification. The modification of Honda to remove the essential alcohol kojic acid component would render the Honda composition unsatisfactory for its intended purpose.

In addition, the disclosure in Honda that a humectant can be added as an optional ingredient does not support the position that the disclosure in Hughes et al. can be used to modify the Honda composition to obtain Applicant's claimed composition plus the excluded GRAS flavored alcohol. As noted in the Action at page 3, lines 4-6, Honda also discloses as another carrier, extracts such as camphor. Hughes et al. discloses camphor under the list of useful anesthetic or antipruritic drugs that also includes benzyl alcohol (column 9, lines 41-48). Accordingly, the motivation to include lactic acid in the Honda composition would similarly apply to including benzyl alcohol in the Honda composition. As Applicant's claimed antimicrobial composition consists essentially of a mixture free of benzyl alcohol, the claimed exclusion of benzyl alcohol is another claim limitation not taught or suggested by the combination of Honda and Hughes et al.

Accordingly, for the reasons set forth above, the rejection of claims 46, 57-58, 61, 63, 64 and 66-70 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of United States Patent No. 5,750,563 to Honda, in view of United States 5,322,689 to Hughes et al. is untenable and should be withdrawn.

**B.     Response to Rejection of claim 65 under 35 U.S.C. § 103**

Claim 65 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of Honda, in view of United States Patent No. 5,416,075 to Carson et al. Carson et al. is relied on as disclosing antimicrobial emulsions comprising extracts and antimicrobial compounds. The extracts are identified as including essential oils, including camphor, orange oil and anise oil. Carson et al. does not disclose Applicant's claimed antimicrobial composition consisting essentially of a mixture free of benzyl alcohol, containing from 0.1 to 90% by weight of a polyphenol selected from the group consisting of tannins and tannic acid, 0.1 to 30% by weight of lactic acid, and that the mixture contains no other generally recognized as safe flavored alcohols. Accordingly, Carson et al. provides no motivation to one of ordinary skill in the art to modify the Honda composition to obtain Applicant's composition. Hence, a rejection of claim 65 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of United States Patent No. 5,750,563 to Honda, in view of United States Patent No. 5,416,075 to Carson et al. is untenable and should be withdrawn.

**IV. Conclusion**

It is believed that the above Amendment and Remarks constitute a complete Response under 37 C.F.R. § 1.111 and that all grounds for objection stated in the Action have been adequately rebutted or overcome. A Notice of Allowance in the next Action is therefore requested. The Examiner is requested to telephone the undersigned counsel if any matter that can be expected to be resolved in a telephone interview is believed to impede the allowance of pending claims 46, 57-58, 61, and 63-70 of Application Serial No. 09/743,883.

Respectfully submitted,

**PAUL AND PAUL**

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/John S. Child, Jr./  
John S. Child, Jr.  
Registration No. 28833  
2000 Market Street  
Suite 2900  
Philadelphia, PA 19103-3229  
Telephone: (215) 568-4900  
Facsimile: (215) 568-5057  
Attorneys for Applicant

**CORRESPONDENCE ADDRESS:**

**Customer No. 27569**

John S. Child, Jr., Esquire  
Paul and Paul  
2000 Market Street  
Suite 2900  
Philadelphia, PA 19103-3229  
Paul and Paul Order No. 5785